



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Spring Valley Family Pharmacy; Decision and Order

On April 12, 2021, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, Government), issued an Order to Show Cause (hereinafter, OSC) to Spring Valley Family Pharmacy (hereinafter, Registrant) of Gallipolis, Ohio. OSC, at 1. The OSC proposed the revocation of Registrant’s Certificate of Registration (hereinafter, registration) No. FS7068249. *Id.* It alleged that Registrant “currently lacks state authority to handle controlled substances.” *Id.* (citing 21 U.S.C. 824(a)(3)).

Specifically, the OSC alleged that on or about October 2, 2020, Registrant permanently and voluntarily surrendered its Ohio state pharmacy license to the State of Ohio Board of Pharmacy with the surrender effective on October 5, 2020. *Id.* at 2. According to the OSC, Registrant permanently and voluntarily surrendered its Ohio state pharmacy license “after its owner and primary operator, Brandon O’Callaghan, permanently and voluntarily surrendered his state pharmacist license after testing positive for controlled substances in violation of a Board Order.” *Id.* The OSC concluded that because Registrant is “currently without authority to handle controlled substances in Ohio, the state in which [Registrant] is registered with DEA DEA must revoke [Registrant’s] registration” *Id.*

The OSC notified Registrant of the right to request a hearing on the allegations or to submit a written statement, while waiving the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 2-3 (citing 21 CFR 1301.43). The OSC also notified Registrant of the opportunity to submit a corrective action plan. *Id.* at 3 (citing 21 U.S.C. 824(c)(2)(C)).

Adequacy of Service

In a Declaration dated June 8, 2021, a Diversion Investigator (hereinafter, the DI) assigned to the Charleston District Office, Louisville Field Division, stated that she and a Tactical Diversion Squad Group Supervisor traveled to the residence of Brandon O’Callaghan, the former owner and pharmacist for Spring Valley Family Pharmacy, in Winfield, West Virginia on April 26, 2021. Request for Final Agency Action, dated June 9, 2021 (hereinafter, RFAA), Exhibit (hereinafter, RFAAX) 3 at 1. The DI stated that on that date, she “personally handed Mr. O’Callaghan a copy of the [OSC].” *Id.* The DI also stated that “Mr. O’Callaghan signed Form DEA-12 Receipt for Cash or Other Items, which indicated that he received a copy of the [OSC].” *Id.* In her Declaration, the DI included a true and correct copy of the DEA-12 that Mr. O’Callaghan signed. RFAAX 3, Appendix (hereinafter, App.) A.

The Government forwarded its RFAA, along with the evidentiary record, to this office on June 10, 2021. In its RFAA, the Government represents that “[Registrant] has not submitted a timely request for a hearing in this matter.”¹ RFAA, at 1.

The Government seeks to “revoke the [DEA COR] of [Registrant] because [Registrant] lacks authority to handle controlled substances in the State of Ohio, the state where [Registrant] is registered with DEA.” *Id.* The Government requests that the Administrator revoke Registrant’s DEA registration. *Id.* at 5.

Based on the DI’s Declaration, the Government’s written representations, and my review of the record, I find that the Government accomplished service of the OSC on Registrant on April 26, 2021. I also find that more than thirty days have now passed since the Government accomplished service of the OSC. Further, based on the Government’s written representations, I find that neither Registrant, nor anyone purporting to represent the Registrant, requested a hearing, submitted a written statement while waiving Registrant’s right to a hearing, or submitted

¹ The Government included a second DI Declaration, dated June 9, 2021, in its RFAA, which stated that “DEA has not received any correspondence from Spring Valley Family Pharmacy concerning the [OSC].” RFAAX 4, at 2.

a corrective action plan. Accordingly, I find that Registrant has waived the right to a hearing and the right to submit a written statement and corrective action plan. 21 CFR 1301.43(d) and 21 U.S.C. 824(c)(2)(C). I, therefore, issue this Decision and Order based on the record submitted by the Government, which constitutes the entire record before me. 21 CFR 1301.43(e).

FINDINGS OF FACT

Registrant's DEA Registration

Registrant is the holder of DEA Certificate of Registration No. FS7068249 at the registered address of 448 Jackson Pike, Gallipolis, OH 45631. RFAAX 1 (Certificate of Registration). Pursuant to this registration, Registrant is authorized to dispense controlled substances in schedules II through V as a retail pharmacy. *Id.*

The Status of Registrant's State License

On October 5, 2020, the State of Ohio Board of Pharmacy (hereinafter, Board) issued a "Settlement Agreement with the State of Ohio Board of Pharmacy" (hereinafter, Settlement Agreement). RFAAX 4, App. A. According to the Settlement Agreement, the Board had initiated an investigation of Registrant, a pharmacy licensed as a "Terminal Distributor of Dangerous Drugs," and Brandon O'Callaghan, owner and operator of Registrant, related to Mr. O'Callaghan's "illicit drug usage and failure to ensure [Registrant] [met] minimum standards and maintained sanitary compounding area conditions to ensure public safety." *Id.* at 1. The Settlement Agreement states that on or about June 19, 2019, the Board sent Registrant a Summary Suspension/Notice of Opportunity for Hearing and that Registrant subsequently requested a hearing by and through counsel on or about July 15, 2019. *Id.* The hearing was held on or about November 5, 2019, and resulted in a Board Order that placed both Registrant's license and Mr. O'Callaghan's license on indefinite suspension subject to certain conditions. *Id.* at 2. According to the Settlement Agreement, on or about January 8, 2020, Mr. O'Callaghan violated the terms of the Order by "testing positive for amphetamine (454 ng/ml) and methamphetamine (2368 ng/ml)." *Id.* According to the Settlement Agreement, Mr. O'Callaghan

subsequently surrendered his pharmacy license on May 5, 2020, and thus Registrant “no longer [had] a Responsible Person or owner that [was] lawfully allowed to possess” its license. *Id.* Under the terms of the Settlement Agreement, Registrant permanently and voluntarily surrendered to the Board its license and registration. *Id.* at 2.

According to Ohio’s online records, of which I take official notice, Registrant’s state pharmacy license remains inactive.² https://elicense.ohio.gov/OH_HomePage (last visited date of signature of this Order). Accordingly, I find that Registrant is not currently licensed to dispense controlled substances in Ohio, the state in which Registrant is registered with the DEA.

DISCUSSION

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (hereinafter, CSA) “upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.” With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner’s registration. *See, e.g., James L. Hooper, M.D.*, 76 FR 71,371 (2011), *pet. for rev. denied*, 481 F. App’x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.*, 43 FR 27,616, 27,617 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress defined the term “practitioner” to mean “a pharmacy . . . or other person licensed, registered, or otherwise

² Under the Administrative Procedure Act, an agency “may take official notice of facts at any stage in a proceeding – even in the final decision.” United States Department of Justice, Attorney General’s Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), “[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.” Accordingly, Registrant may dispute my finding by filing a properly supported motion for reconsideration of finding of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by e-mail to the other party and to Office of the Administrator, Drug Enforcement Administration at dea.addo.attorneys@dea.usdoj.gov.

permitted, by . . . the jurisdiction in which [it] practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.” 21 U.S.C.

802(21). Second, in setting the requirements for obtaining a practitioner’s registration, Congress directed that “[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.” 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner’s registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper*, 76 FR at 71,371-72; *Sheran Arden Yeates, M.D.*, 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.*, 58 FR 51,104, 51,105 (1993); *Bobby Watts, M.D.*, 53 FR 11,919, 11,920 (1988); *Frederick Marsh Blanton*, 43 FR at 27,617.

Under Ohio law, a terminal distributor of dangerous drugs “means a person who is engaged in the sale of dangerous drugs³ at retail . . . ” and “includes pharmacies . . . and all other persons who procure dangerous drugs for sale or other distribution by or under the supervision of a pharmacist . . . or any other person authorized by the board of pharmacy.” Ohio Rev. Code Ann. § 4729.01(Q) (West 2021). Further, Ohio law provides that, other than a licensed terminal distributor of dangerous drugs and other inapplicable exceptions, “no person shall do any of the following: (a) sell or distribute, at retail, dangerous drugs; (b) possess for sale, at retail, dangerous drugs; (c) possess dangerous drugs.” Ohio Rev. Code Ann. § 4729.51(E)(1) (West 2021).

Here, the undisputed evidence in the record is that Registrant surrendered its license as a terminal distributor of dangerous drugs in Ohio. As already discussed, a terminal distributor of

³ The definition of “dangerous drugs” includes a drug that “may be dispensed only upon a prescription” under revised code section 3719. Ohio Rev. Code. Ann. § 3719.41 states that the state board of pharmacy shall adopt rules establishing the schedules of controlled substances “incorporating the five schedules of controlled substances under the federal drug abuse control laws.”

dangerous drugs must be licensed to be authorized to possess or distribute controlled substances in Ohio. Thus, because Registrant permanently and voluntarily surrendered its Ohio state pharmacy license and, therefore, is not authorized to dispense controlled substances in Ohio, Registrant is not eligible to maintain a DEA registration. Accordingly, I will order that Registrant's DEA registration be revoked.

ORDER

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. FS7068249 issued to Spring Valley Family Pharmacy. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of Spring Valley Family Pharmacy to renew or modify this registration, as well as any other pending application of Spring Valley Family Pharmacy for additional registration in Ohio. This Order is effective **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

D. Christopher Evans,

Acting Administrator.

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